RESEARCH ADVISORY COUNCIL

RESEARCH PROPOSAL PROGRESS REPORT

RAC #

Sponsor/Collaborator # None

TITLE:

CURRENT PRINCIPAL INVESTIGATOR(S):

CURRENT CO-INVESTIGATOR(S):

APPROVAL DATE:

PROPOSED DURATION:

APPROVING COMMITTEE(S):

LAST PROGRESS REPORT DATE:

SPONSOR/COLLABORATOR(S):

TOTAL BUDGET:

SOURCE OF FUNDS:

ACCUMULATIVE AMOUNT BILLED:

ACCUMULATIVE AMOUNT RECEIVED:

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1 HAS THE RESEARCH PROPOSAL BEEN MODIFIED?

No ☐

Yes ☐ **Explain**

2 HAVE THE INVESTIGATORS CHANGED?

No ☐

Yes ☐ **Explain**

3 APPROVED AIMS OF THE RESEARCH PROPOSAL:

4 PROGRESS DURING THE REPORT PERIOD:

(Please provide sufficient information, including preliminary findings if appropriate, to clearly indicate progress to date. Indicate accomplishments during this report period. Refer to previous reports as necessary. Address all of the approved research aims).

5 PUBLICATIONS & RELATED ACTIVITIES:

(Please list all presentations, abstracts, and publications which are related to this proposal. Please include a copy of any publication not previously submitted to the Research Advisory Council. Mark with an asterisk the publications that have been listed in progress or final reports of other proposals).

6 DID YOU ADHERE TO THE MANUSCRIPT AUTHORSHIP GUIDELINES REGARDING ALL PUBLICATIONS/ABSTRACTS RESULTING FROM THIS PROPOSAL?

(N Eng J Med 1997; 336:309-315)

Yes ☐ **Not applicable** ☐
No ☐ **Explain**

7 FOR HOW MANY MONTHS IS THE CONTINUED APPROVAL REQUESTED? (up to 12 months at a time)

8 BRIEFLY OUTLINE THE RESEARCH PLANS FOR THE NEXT APPROVAL PERIOD.

FOR ALL RESEARCH STUDIES INVOLVING HUMAN SUBJECTS:

(Human subject is defined as an individual about whom an investigator obtains (i) data through intervention or interaction with the individual, or (ii) identifiable private information).

9 HAVE YOU FULLY ADHERED TO THE GOOD CLINICAL PRATICE GUIDELINES?
(copy available in RAC Office)

Yes ☐
No ☐ Explain

10 DID ANY ADVERSE EVENTS OCCUR?
(Any untoward or unfavourable occurence experienced by a subject participating in a clinical study)

No ☐
Yes ☐ If yes, the attached Human Subject Adverse Event Report must be completed.

Were they expected?	Were they serious?
No ☐	No ☐
Yes ☐	Yes ☐

11 DID YOU OBTAIN AND MAINTAIN RECORDS OF PROPER INFORMED CONSENT FROM ALL STUDY SUBJECTS?

Yes ☐
No ☐ Explain

(attach a copy of the consent form in current use)

12 HOW MANY SUBJECTS HAVE BEEN ENROLLED? ____
(Please complete the attached Human Subject Enrollment Report)

13 HOW MANY ENROLLED SUBJECTS WITHDREW? ____
List reasons for withdrawal:

14 IS THERE ANY NEW INFORMATION WHICH MAY AFFECT THE BENEFIT/RISK RATIO OF THE RESEARCH STUDY?

No ☐
Yes ☐ Explain

Signature Principal Investigator: _____ Date: _____

HUMAN SUBJECT ADVERSE EVENT REPORT

1. An adverse event is defined as any untoward or unfavorable occurence experienced by a subject participating in a clinical study. List each type of adverse event observed during the conduct of the study (*ie,* headache, rash, social or psychological stress, loss of privacy, break of confidentiality). Mark by an asterisk adverse events observed in other centres (if this is a multi-centre study).

2. List subjects by medical record number (MRN) and adverse events. Numeric identifiers or initials are acceptable only in the absence of MRN. Characterize the adverse events as to:
   a. Severity - mild, moderate, severe
   b. Recovery - total, partial, none
   c. Relationship to protocol - none, possible, probable, definite

MRN	Adverse Event	Severity of Event	Recovery from Event	Relationship to Protocol

HUMAN SUBJECT ENROLLMENT FORM

1. Cumulative number of subjects enrolled during lifetime of the Project

   Dates: From: To:

2. Number of subjects enrolled during last approval year:

   Dates: From: To:

   List the MRN # (numeric identifiers or initials are acceptable only in the absence of a MRN) of all human subjects enrolled at KFSH&RC during lifetime of the Project. Identify human subjects enrolled in the last approved year by an asterisk, using additional pages if necessary.
